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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

January 16, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 13

Leo J. Utecht
President
Pro-Tect Medical Products, Inc.
9905 Hamilton Road
Eden Prairie, Minnesota 55344

Dear Mr. Utecht:

We are writing to you because on December 23 and 30, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving wound dressings that are made and marketed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), a product is considered to be a medical device if it is used to diagnose or treat a medical condition or is intended to affect the structure or function of the body. Wound dressings are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to the Quality System Regulation specified in Title 21, Code of Federal Regulations (CFR), Part 820, in the methods used in, and the facilities and controls used for, the design, manufacturing, packaging, labeling, storage, installation, and servicing of medical devices. This regulation sets forth the Good Manufacturing Practice (GMP) requirements for medical devices.

In legal terms, your wound dressing products are adulterated under Section 501(h) of the Act because:

- They were not manufactured in compliance with the GMP regulation in place at the time they were manufactured, and
- Your current operations fail to comply with the Quality System Regulation.

Our inspection found violations of the Quality System Regulation, as noted below.

1. The quality system lacks numerous required elements. For example:
   - A quality policy has not been established (21 CFR 820.20).
   - Procedures have not been established for training of personnel (21 CFR 820.25), document control (21 CFR 820.40), acceptance activities (21 CFR 820.80), nonconforming product (21 CFR 820.90), and corrective and preventative action (21 CFR 820.100).

2. There are no established procedures for internal quality audits and no internal audits have been conducted (21 CFR 820.22).

Additional GMP deficiencies in purchasing controls (21 CFR 820.50) and document controls (21 CFR 820.40) are noted in the form FDA-483 that was issued to you on December 30, 1997. Refer to the FDA-483 for details. Please note that "establish," as defined in 21 CFR 820, means to "define, document (in writing or electronically), and implement."

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If

the causes are determined to be system problems, you must promptly initiate permanent corrective actions. Your corrective actions should extend to all applicable products and product lines.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president and most responsible individual at Protect Medical Products, it is ultimately your responsibility to ensure that devices manufactured at your facility are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Acting Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of current Good Manufacturing Practices for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, please feel free to contact Mr. Philips at (612) 334-4100 ext. 192.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/ccl